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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,531	02/21/2002	Denis Martin	484112.423	3055

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/078,531	MARTIN ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54, 58 and 59* is/are rejected.

7)☒ Claim(s) *55-57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-10-07 and 10-31-07 have been entered.

The amendment filed 9-10-07 has been entered into the record. Claims 1-53 have been cancelled. Claims 54-59 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The objection to the use of the trademarks has been noted in this application has been withdrawn in view of Applicants amendments.

The rejection of claims 17, 19-21, 35, 37-38 and 40-53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn based on the amendment to the claims.

The rejection of claims 17, 19-21, 35, 37-38 and 40-53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

at the time the application was filed, had possession of the claimed invention is withdrawn based on the amendment to the claims.

The rejection of claims 17, 19-21, 35, 37-38 and 40-53 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptide from *S. pyogenes* having at least 95% identity to the full-length amino acid sequence as set forth in SEQ ID NO:2, an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 lacking the leader sequence consisting of amino acid residues 1 to 21 of SEQ ID NO:2 or an isolated polypeptide of SEQ ID NO:2 wherein the N-terminal methionine residues is deleted and pharmaceutical compositions comprising an isolated polypeptide of SEQ ID NO:2 lacking the leader sequence consisting of amino acid residues 1 to 21 of SEQ ID NO:2 or an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 wherein the N-terminal methionine residues is deleted, it does not reasonably provide enablement for polypeptides comprising 10 contiguous amino acids, chimerics, multimers or epitopes or at least 70%, 90% variants, and non-natural variants of polypeptides that are at least 95% identical with a fragment or the full length of SEQ ID NO:2, chimerics or multimers thereof is withdrawn based on the amendment to the claims.

The rejection of claims 17, 19, 35 and 36 under 35 U.S.C. 102(b) as anticipated by Dixon et al, PIR_79 Database Accession Number T51594, Dixon et al, August 18, 2000 is maintained for reasons made of record is withdrawn based on the amendment to the claims.

The rejection of claims 17, 19, 35 and 36 under 35 U.S.C. 102(b) as anticipated by McDonald on et al, PIR_79 Database Accession Number JE0176, July 03, 1998 is withdrawn based on the amendment to the claims.

The rejection of claims 17, 19, 20, 21, 30, 35-38, 41, 42 and 43 under 35 U.S.C. 102(a) as being anticipated by Le Page et al (WO 01/32882, published May 19, 2001) is withdrawn in view of the amendment to the claims.

Rejections Maintained

Double Patenting

Claims 54-59 of this application conflict with claims 18-20, 22 and 35-38 of Application No.10/476,614 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 54 and 57 stand provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 18 and 37 of copending Application No. 10/476,614. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Applicants are claiming the same structures, the same structure have the same function, therefore despite the minor difference in wording, the claims are identical.

Claim 54 is rejected under 35 U.S.C. 102(a) as being anticipated by Ferretti et al (PNAS, 98(8):4658-4663, April 10, 2001) is maintained for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. A single claim is assigned a single date, where the application document fulfills the requirement of 35 USC 112, 1st paragaraph. It has been determined that claim 54 is only entitled to the instant filing date because the provisional document fails to comply with the written description requirement for the variants. As such, Ferreti et al reads on the genus claim as the genus lacked written description and was not enabled in the provisional document.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37

CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferretti et al (PNAS, 98(8):4658-4663, April 10, 2001) in view of Campbell et al IN:Monoclaonal Antibody Technology, Elsevier Science Publishers, 1984, Chapter 1, section 1.3.4. page 29 and Harlow et al (Cold Spring Harbor Press, 1988, pages 72-73, and 76-77).

Ferretti et al teaches a polypeptide that is 100% identical as compared to SEQ ID NO:2. Ferretti et al differ by not putting the polypeptide in a pharmaceutical carrier, diluent or adjuvant.

Campbell et al teaches that the potential of monoclonal antibodies in basic research is considerable and that in principle they can resolve a single protein from a complex mixture or a single epitope on a complex macromolecule. Campbell also teaches that "It is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective to their application).

Harlow et al teach conventional methods of making monoclonal antibodies by placing the protein/peptide in a composition with an adjuvant an immunizing an animal as a first step in the process.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to mix the polypeptide of Ferretti et al with an adjuvant according to Harlow et al to make an immunogenic composition to make antibodies because

Campbell et al teach that it is now customary to both clone the gene and make monoclonal antibodies to the polypeptide (sometimes without a clear objective for their application).

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over LePage et al, (US 2003/0170782, with priority to 9-7-2000) in view of Harlow et al, Antibodies:A Laboratory Manual, Cold Spring Harbor Press, 1988; Chapter 5, pages 72-73, 76-77.

LePage et al teach a polypeptide (SEQ ID NO:24) that is 74.4% identical as compared with SEQ ID NO:2 (see alignment) which has multiple regions of 100% identity comprising at least 10 contiguous amino acids of SEQ ID NO:2. LePage et al teach that the present invention provides Group B streptococcus proteins/polypeptides or fragments or derivatives thereof [0010]. LePage et al teach vaccines comprising the proteins in a pharmaceutically acceptable carrier (see [0177]). LePage et al contemplated peptides and fragments of the disclosed sequences and indicated that such could be used in immunogenic compositions and to make antibodies [0047]. LePage et al differ by not using a fragment of SEQ ID NO:2 consisting of at least 10 continguous amino acids.

Harlow et al teach conventional methods of making antibodies using oligopeptide immunogens. Harlow et al teach that peptides of approximately 10 residue should be used as a lower limit for coupling and that the safest choice will be to prepare multiple small peptides of 10-15 amino acids in length from various regions of the peptide sequence.

It would have been *prima facie* obvious to one skill in the art at the time the invention was make all the peptide fragments consisting of 10-15 amino acids of the protein according to LaPage et al to make antibodies because Harlow et al teach that the safest choice for making antibodies would be to prepare multiple small peptide sequence of 10-15 amino acids in length to make antibodies and LePage et al teach that fragments of the disclosed polyeptides can be used in immunogenic compositions and to make antibodies

Status of Claims

Claims 55-57 are objected to as depending from rejected claims. Claims 54, 58 and 59 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner

Art Unit 1645